

PATENT APPLN. NO. 10/562,059
RESPONSE UNDER 37 C.F.R. § 1.116

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REMARKS

Claim 2 has been amended to limit the disialoundecaoligosaccharide of the asparagine-linked disialoundecaoligosaccharide-fatty acid of the present invention to the oligosaccharide disclosed in paragraph [0014] of the present specification and in Fig. 2, and which is used in the embodiments of the present invention as described in the specification.

Claim 8 has been amended to recite a drug comprising at least one selected from the asparagine-linked disialoundecaoligosaccharide-fatty acid amide of claim 2 and asparagine-linked disialoundecaoligosaccharide having formula (3).

New claims have been added to the application to recite a method of treating viral infection by administering a therapeutically effective amount of an asparagine-linked disialoundecaoligosaccharide-fatty acid amide of claims 2-4 (claims 21-23, respectively); a therapeutically effective amount of a composition of claims 5, 6, 12, 13, 15 and 16 (claims 24-29, respectively); and a therapeutically effective amount of a drug of claims 7 and 8 (claims 30 and 31, respectively) to a subject in need of such treatment.

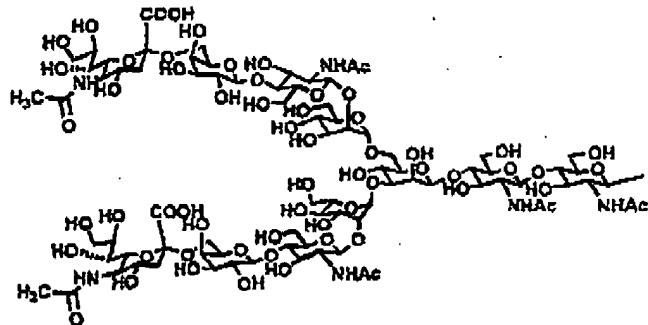
Claim Rejections - 35 USC § 112

Referring to the Action, claims 2-8, 12, 13, 15 and 16 are

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rejected under 35 U.S.C. § 112, first paragraph, for lack of sufficient enabling support for the full scope of the claims. As noted above, claim 2 has been amended to limit the disialoundecaoligosaccharide of the asparagine-linked disialoundecaoligosaccharide-fatty acid in claim 2 to the oligosaccharide shown below and which is described in paragraph [0014] of the specification and in Fig. 2, and is used in the embodiments in the specification.



The asparagine-linked disialoundecaoligosaccharide-fatty acid amide now recited in the claims is believed to comply with the description and enablement requirements of 35 U.S.C. § 112, first paragraph, and removal of the 35 U.S.C. § 112 rejection is respectfully requested.

Claim Rejections - 35 USC § 102

Claims 2-8, 12, 13, 15 and 16 are also rejected under 35

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U.S.C. § 102(b) as being anticipated by Michel et al., "Model Gycococonjugates consisting of biantennary N-glycans coupled to fatty acids: Synthesis and X-ray diffraction study" *Makromol. Chem.* (1985) Vol. 186, (hereinafter "Michel"). This is the same rejection that was made in the first Office Action.

In response to the first Office Action, Applicants argued that the claimed conjugate contains only an asparagine connected to glycan, while the prior art compounds include dipeptides and larger peptides containing multiple amino acids.

In the Final Action the Office states, however, that the claimed conjugate is not limited to asparagine mono-amino acid conjugate.

The applicant has amended claim 2 to precisely recite that the conjugate does not include amino acids other than asparagine linked to oligosaccharide.

The Office also states that Michel does include conjugates linked by asparagine alone (page 7, line 21). However, Michel merely describes that the peptide part of a mixture of serum glycoproteins contains, for 1 mol of asparagines, 0.3 mol of glycine, 0.25 mol of glutamate, 0.2 mol of serine and traces of alanine and proline. What can be said based on this amino acid ratio is merely that there is a possibility that the glycopeptides

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molecule contains, *on the average*, about one amino acid residue in addition to asparagine at the glycosylation site. However, the ratio, itself, does not show that the mixture of serum glycoproteins includes any conjugates linked by asparagine alone.

Although not expressly described, given the fact that Michel was published in 1985, it is likely that the amino acid ratio was determined by amino-acid analysis, which does not determine the structure of the glycoprotein. Therefore, for example, if there is a conjugate that includes more than two asparagines, the ratio of asparagine will be more than the total ratio of other amino acids. Furthermore, it is also known by a person skilled in the art that the amino-acid analysis does not distinguish Asn from Asp.

Based on the above, it cannot be concluded that Michel shows the structure of the glycoprotein contained by a mixture of serum and that the conjugate of Michel necessarily possesses the characteristics of the claimed conjugate.

It is well-established that a claim limitation or limitations must necessarily be included in a prior art reference in order for the reference to anticipate within the meaning of 35 U.S.C. § 102. The fact that a limitation might result from the disclosure of a reference is not sufficient.

Accordingly, Michel is not sufficient to support the rejection

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of the claims within the meaning of 35 U.S.C. § 102 and removal of the rejection is in order.

Claim Rejections - 35 USC § 103

The 35 U.S.C. § 103(a) rejection depends on the sufficiency of Michel to support the rejection under 35 U.S.C. § 102(b). Since Michel has been shown to be insufficient to support the 35 U.S.C. § 102(b) rejection, the cited art is insufficient to support a case of *prima facie* obviousness of the rejected claims under 35 U.S.C. § 103(a) and removal of the rejection is also in order.

Comment re New Claims

None of the prior art, including the prior art cited in the Final Action, discloses that the asparagine-linked disialoundecaoligosaccharide-fatty acid amide of the present invention is effective against viral infections. Therefore, the claims added to the application are believed to be patentable under 35 U.S.C. § 102 and 35 U.S.C. § 103(a).

Additionally, in the first Office Action, although the claims directed to a drug for preventing and/or curing influenza virus infectious diseases were rejected under 35 U.S.C. § 112, the Office stated that "the specification, while being enabling for a drug for treating influenza virus infection, does not reasonably provide enablement requirement for a drug for preventing and/or curing

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viral infections" (Office Action dated December 21, 2007, page 5, last line, to page 6, line 2, emphasis added). Applicants believe, therefore, that new method of treatment claims are also patentable under 35 U.S.C. § 112.

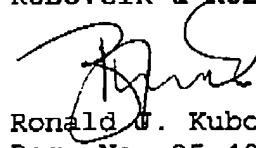
A Notice of Allowability of the claims now in the application is respectfully requested.

The foregoing is believed to be a complete and proper response to the Office Action dated September 8, 2008.

In the event that this paper is not considered to be timely filed, applicants hereby petition for an appropriate extension of time. The fee for any such extension and any additional required fees may be charged to Deposit Account No. 111833.

Respectfully submitted,

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